

REMARKS

Reconsideration of the present application is requested in view of the foregoing amendment and following remarks.

I. Claim Amendments

Claim 1 is amended to clarify that the variant protease consists essentially of the amino acid sequence of GG36 protease. Support for the amendment can be found, *e.g.*, in the original claims and at page 2, lines 13-15; page 5, lines 1-3; page 20, lines 15-18; and page 21, lines 19-23, of the published PCT application.

Claim 1 is also amended to clarify that equivalent amino acid positions are determined by primary amino acid sequence alignment. Support for the amendment can be found, *e.g.*, at page 8, lines 3-23 and Figs. 3A and 3B of the published PCT application.

Claim 1 is further amended to specify that that the variant has protease activity under detergent wash conditions. Support for the amendment can be found, *e.g.*, at page 29, line 2 – page 31, line 19 (including Table 2) of the published PCT application.

Claim 2 is amended to delete language relating to wash performance and to conform the remaining language to that of the other claims.

Claims 15 and 16 are amended to correct minor technical errors.

No new matter has been added by these amendments.

II. Rejections under 35 U.S.C. § 112, first paragraph (enablement)

The claims were rejected under 35 U.S.C. §112, first paragraph, as allegedly not meeting the enablement requirement.¹ The rejection appears to be based on (i) the Examiner's interpretation of the claim language to encompass amino acid substitutions, additions, and deletions, other than those recited in claim 1, and (ii) the absence of an explicit requirement that the variant possess protease activity.

The foregoing amendments are believed to address the rejections. Claim 1, from which all other claims depend, has been amended to require that the variant protease consists essentially of the amino acid sequence of GG36 protease except for the recited substitutions, thereby addressing the Examiner's concern that the claim encompasses "arbitrary amino acid substitutions, additions or deletions in non-specific polypeptides that might be aligned with the amino acid sequence of SEQ ID NO:2." Office Action at 2. Claim

¹ The rejection referred to claims 1-3 and 5-16; however, claims 1-3 and 15-18 were (and remain) pending in the application.

1 has also been amended to require that the variant protease has activity under detergent wash conditions, thereby addressing the Examiner's concern that the claims encompasses variants that lack protease activity.

Withdrawal of the rejections is respectfully requested.

III. Rejections under 35 U.S.C. § 102

Claims 1-3 and 15-18 were rejected under 35 U.S.C. §102(e) and §102(f), as allegedly being anticipated by Estell *et al.* (USPN 7,332,320; U.S. Pat. Pub. No. 2005/0148059).² The basis of the rejections appears to be that the claims "require no particular degree of structural relationship to the amino acid sequence set forth in SEQ ID NO:6" and, therefore, read on chimeric subtilisins described in the reference. Office Action at 3.

The clarifications introduced by the foregoing amendments to claim 1, from which all other rejected claims depend are believed address the rejection. As amended, claim 1 now requires that the variant protease comprises an amino acid sequence consisting essentially of the amino acid sequence of GG36 protease. Accordingly, the chimeric GG36-BPN' variants described in Estell *et al.* (e.g., at col. 12, lines 16-25) do not meet the structural requirements of the present claims. For this reason alone, Estell *et al.* does not anticipate the variant protease defined by the pending claims.

Dependent claims 2 and 3 are further distinguished from Estell *et al.* because these claims require the protease variant to exhibit increased stability (claim 2) or thermostability (claim 3) compared to a reference protease (GG36; SEQ ID NO:6). Estell *et al.* describe the immunogenicity of variant proteases and further mention that some mutations may modulate stability (including N218S; see, e.g., Example 6). However, Estell *et al.* do not describe a protease variant comprising a combination of the V26T or V26S substitution with the N218S substitution in a protease that otherwise consists essentially of the GG36 amino acid sequence, nor that such a variant would have increased stability (including thermostability) compared to GG36. The only mention of GG36 in Estell *et al.* is with respect to the aforementioned chimeric protease which does not meet the structural requirements of independent claim 1. For these additional reasons, dependent claims 2 and 3 are further distinguished from Estell *et al.*

² Note that reference to U.S. Pat. Pub. No. 2005/0148159 in previous Office Actions was incorrect.

For at least the above reasons, it is apparent that Estell *et al.* does not describe the claimed variant protease. Withdrawal of the rejections under 35 U.S.C. §102(e) and §102(f) is respectfully requested.

IV. Conclusion

In view of the foregoing amendments and remarks, Applicant submits that the application is fully in condition for allowance. Early notice to that effect is earnestly requested. If the Examiner has any questions regarding the present application he is encouraged to contact the undersigned.

Respectfully submitted,

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Date

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